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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

WORLEY, CATHY KINGDON

ART UNIT	PAPER NUMBER
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1638

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/683,399	Applicant(s) MARTINELL ET AL.	
	Examiner Cathy K. Worley	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendment filed May 29, 2007 has been entered.
2. Claims 20 and 21 have been cancelled.

Claims 1-19 are pending and are examined in the present office action.

3. In light of the Applicant's arguments in the papers filed on May 29, 2007, the previous rejections are withdrawn.
4. Upon further searching and examination, new art is being applied for new rejections; therefore the finality of the Office Action mailed on Feb. 27, 2007 is withdrawn.
5. The text of those sections of Title 35, U.S. Code not included in this office action can be found in a prior office action.

Claim Rejections - 35 USC § 103

6. Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martinell et al (US Patent No. 5,914,451, issued on June 22, 1999) in view of Jefferson et al (The EMBO Journal (1987), Vol. 6, pp.3901-3907).

The claims are drawn to a method for early identification of germline transformed plants. The elements recited in the claims are:

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- 1) transforming meristemic or cotyledonary tissue with a plant expressible construct (claims 1 and 16)
- 2) expressible construct confers to the plant insect tolerance, pest tolerance, herbicide resistance, quality enhancement, yield enhancement, stress tolerance, and environmental tolerance (claim 2)
- 3) expressible construct comprises two nucleic acids each encoding a protein (claim 3)
- 4) expressible construct comprises a selectable marker (claim 4)
- 5) construct comprises a gene of interest (claim 17)
- 6) construct comprises the nptII gene (claim 18)
- 7) producing a shoot (claims 1 and 16)
- 8) culturing shoots in presence of kanamycin (claim 16)
- 9) regenerating transformed plant from shoots (claim 16)
- 10) growing roots from the shoot (claim 1)
- 11) growing roots in the presence of a selection agent (claim 5)
- 12) selection agent is kanamycin (claim 6)
- 13) selection agent is glyphosate (claim 7)
- 14) transformation is Agrobacterium or particle-mediated (claims 8 and 19)
- 15) obtaining an extract of transformed root tissue (claims 1 and 16)
- 16) assaying the root extract for the presence of the nucleic acid sequence (claims 1 and 16)

- 17) assay is an assay for a protein (claim 9)
- 18) assay is ELISA, colorimetric, fluorometric, or enzymatic (claim 10)
- 19) assay is for nucleic acid (claim 11)
- 20) assay is PCR, RT-PCR, or southern blot (claim 12)
- 21) plant is dicot, soybean, or cotton (claims 13-15)
- 22) identifying roots that assay positive (claims 1 and 16).

None of these elements are novel (see below for an item-by-item account of references from the prior art that teach these elements), and there is no indication of a particular element that is critical. In the absence of any evidence of criticality or unexpected results, any combination of these elements is an obvious variant of methods that are taught in the prior art. To demonstrate the obviousness of the claimed invention, the Examiner will analyze the fact patterns according to *Graham v. Deere* analysis.

SCOPE AND CONTENT OF THE PRIOR ART – PRIMARY REFERENCE

In the prior art, Martinell et al teach many of the limitations recited in the instant claims. They teach the transformation of soybeans (which are dicots) (see entire document). They teach the use of meristematic tissue for transformation via particle bombardment (see column 8, lines 15-45). They teach culturing the transformed tissue to produce shoots (see column 8, lines 59-67). They teach

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culturing the transformed shoots on bean rooting medium to induce the growth of roots (see column 9, lines 1-17). They teach that the root medium contained 0.025 mM glyphosate, which is an herbicide that is used as a selectable marker for transformants expressing the EPSP gene (see column 9, lines 1-5; and column 5, lines 25-41). Therefore, the roots were grown in the presence of a selection agent that corresponds to the EPSP gene-product which is a protein that confers resistance to glyphosate.

They teach that genetically engineered soybeans can have advantageous qualities; such as higher yields, pest resistance, enhanced nutritional value, and improved storage qualities, which are traits that can be conferred to a soybean by transformation with a plant expressible construct (see column 3, lines 4-11). They teach a plasmid encoding the EPSP gene (referred to as CP4) as well as encoding β -glucuronidase (GUS) (see column 9, Table 1, and lines 46-58); therefore the plant expressible construct taught by Martinell et al comprised two nucleic acid sequence each encoding a protein. They screened for the presence of the protein encoded by the CP4 gene by ELISA (see paragraph bridging columns 9-10).

DIFFERENCES BETWEEN THE CLAIMED INVENTION AND THE PRIOR ART

Martinell et al do not teach obtaining an extract of root tissue from the transformed plant tissue and assaying the extract for the presence of the nucleic acid sequence. They do not teach the detection of a nucleic acid by PCR, RT_PCR, or Southern Blot. They do not teach the NPTII gene or kanamycin selection. They do not teach transformation of cotton.

SCOPE AND CONTENT OF THE PRIOR ART – SECONDARY REFERENCE

In the prior art, Jefferson et al teach the remaining limitations from the claims with the exception of transformation of cotton. They teach obtaining an extract of root tissue from transformed plants and assaying for reporter activity which indicated the presence of the nucleic acid sequence (see page 3903, Figure 2). They teach detection of the nucleic acid by Southern Blot (see page 3904, Figure 3). They teach the NPTII gene which is known in the art to confer resistance to kanamycin (see page 3901, right column). They teach kanamycin selection (see page 3906, right column, second paragraph).

LEVEL OF ORDINARY SKILL IN THE PERTINANT ART

One of ordinary skill in the pertinent art would have had a Ph.D. degree in molecular biology, plant biology, or some other biological science that emphasizes

genetic engineering in plant systems. One of ordinary skill in this art would have been well-read in methods of plant transformation and would have been aware of different methods for transferring nucleic acids into host cells, different selectable markers, different tissues from different plant species, methods for generating shoots and roots and for regenerating whole plants from transformed tissue, and methods of assaying for the presence of the transgene in the resulting transformants. One of ordinary skill in this art would have appreciated that each plant species would have required some routine experimentation to optimize the efficiency of transformation and would have appreciated that different combinations of elements that are known in the art could have been combined to produce an efficient transformation method.

COMBINING PRIOR ART ELEMENTS TO YIELD PREDICTABLE RESULTS

The prior art references relied on teach each element claimed with the exception of transformation of cotton. Transformation of cotton was well-known in the art at the time of filing (see Applicant's reference to McCabe and Martinell in paragraph 0164 on page 21 of the instant specification), and there does not appear to be any recited method steps or recited materials that are specific to the transformation of cotton in the instant claims. Therefore, all elements of the instant invention were known in the art prior to the filing of the instant application.

One of ordinary skill in the art could have combined the elements as claimed, and each of the elements would have performed their known functions.

One of ordinary skill in the art would have predicted that the result would be a reasonably efficient method of transformation for dicots, soybeans, or cotton. Therefore, the results achieved by the instant invention are not unexpected.

APPLICANTS ASSERTIONS AND ARGUMENTS

The Applicant asserts in the specification that the instant invention is a method that is based on the observation that the presence of the gene of interest in the roots indicates a germline transformation event (see paragraph bridging pages 2-3 of the specification). The assertion appears to be related to the difficulties in selection of transgenic plants due to the generation of chimeras which do not pass the transformation event to their progeny (see paragraph bridging pages 1-2 of the specification). Chimeras are one type of "escape" (see page 4, paragraph 0017), and can be thought of as a type of false positive. The Applicant argues that similar false positives are identified by assaying leaf tissue, and this results in wasted resources and time as plants are carried forward that do not give rise to transgenic progeny (see paragraph bridging pages 5-6 of the response filed on May 19, 2005). The Applicant asserts that their analysis of R1 plants from multiple constructs indicated a 75-100% correlation with plants rooting on glyphosate and germline

transformation (see paragraph bridging pages 5-6 of the response filed on May 19, 2005).

As it relates to the limitation in the claims of "obtaining an extract of root tissue from the transformed plant and assaying the extract for the presence of the nucleic acid sequence", this assertion is not supported by data in the instant specification. Table 4 indicates either 70% or 74% correlation between root assay positives and germline positives (see Table 4, bridging pages 20-21 of the specification). Table 3 indicates either 81% or 84% correlation between growing putative transformants on selectable media and germline positives (see Table 3, page 20 of the specification). Therefore, these data do not support any greater correlation between root assay positives and germline when compared to the correlation between growing on selection media and germline positives.

The prior art clearly teaches growing the putative transformants on selectable media. The prior art also teaches assaying extracts from roots for the presence of a transgene. In the absence of any evidence that assaying extracts from roots is a critical step that provides an unexpected result, the claimed method is merely an obvious variant of methods already taught in the prior art that utilize elements already known in the prior art. Therefore, claims 1-19 are unpatentable over Martinell et al in view of Jefferson et al.

7. Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Firoozabady et al (PMB (1987) Vol. 10, pp. 105-116) in view of Jefferson et al (The EMBO Journal (1987), Vol. 6, pp.3901-3907).

The claims are drawn to a method for early identification of germline transformed plants.

None of the elements recited in the claims are novel (see below for an item-by-item account of references from the prior art that teach these elements), and there is no indication of a particular element that is critical. In the absence of any evidence of criticality or unexpected results, any combination of these elements is an obvious variant of methods that are taught in the prior art. To demonstrate the obviousness of the claimed invention, the Examiner will analyze the fact patterns according to *Graham v. Deere* analysis.

SCOPE AND CONTENT OF THE PRIOR ART – PRIMARY REFERENCE

In the prior art, Firoozabady et al teach many of the limitations recited in the instant claims. They teach the transformation of cotton (which is a dicot) (see entire document). They teach the use of cotyledon tissues for transformation via *Agrobacterium tumefaciens* (see page 106, third paragraph, left column). They teach that the tissue was transformed with a plasmid comprising the NPTII gene which produces a protein that confers kanamycin resistance to plants in which it is

expressed, which can be thought of as herbicide resistance (see page 107, Figure 1).

They teach that transformed calli were maintained on kanamycin selection (see paragraph bridging pages 107-108). They teach culturing the transformed tissue to germinate and form plantlets, which are known in the art to comprise shoots and roots (see paragraph bridging pages 107-108).

DIFFERENCES BETWEEN THE CLAIMED INVENTION AND THE PRIOR ART

Firoozabady et al do not teach obtaining an extract of root tissue from the transformed plant tissue and assaying the extract for the presence of the nucleic acid sequence. They do not teach the transformation of meristematic tissues. They do not teach the detection of a protein utilizing ELISA, colorimetric methods, fluorometric methods, or enzymatic methods, nor do they teach the detection of a nucleic acid by PCR, RT_PCR, or Southern Blot. They do not teach a plant expressible construct that comprises at least two nucleic acid sequences each encoding a protein. They do not teach transformation of soybeans. They do not teach a plasmid comprising both a selectable marker and a protein conferring a trait to a transformed plant. They do not teach growing roots in the presence of a selection agent. They do not teach the use of glyphosate as a selection agent.

SCOPE AND CONTENT OF THE PRIOR ART – SECONDARY REFERENCE

In the prior art, Jefferson et al teach the remaining limitations from the claims with the exception of transformation of soybeans, transforming meristematic tissue, and the use of glyphosate as a selection agent. They teach obtaining an extract of root tissue from transformed plants and assaying for reporter activity which indicated the presence of the nucleic acid sequence (see page 3903, Figure 2). They teach that this assay is a flurometric assay for enzyme activity (see page 3906, right column). They teach detection of the nucleic acid by Southern Blot (see page 3904, Figure 3). They teach the NPTII gene which is known in the art to confer resistance to kanamycin (see page 3901, right column). They teach kanamycin selection which comprises growing roots in the presence of kanamycin (see page 3906, right column, second paragraph). They teach a plasmid that comprises two nucleic acids that each encode a protein (see page 3902, Figure 1).

LEVEL OF ORDINARY SKILL IN THE PERTINANT ART

One of ordinary skill in the pertinent art would have had a Ph.D. degree in molecular biology, plant biology, or some other biological science that emphasizes genetic engineering in plant systems. One of ordinary skill in this art would have been well-read in methods of plant transformation and would have been aware of

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different methods for transferring nucleic acids into host cells, different selectable markers, different tissues from different plant species, methods for generating shoots and roots and for regenerating whole plants from transformed tissue, and methods of assaying for the presence of the transgene in the resulting transformants. One of ordinary skill in this art would have appreciated that each plant species would have required some routine experimentation to optimize the efficiency of transformation and would have appreciated that different combinations of elements that are known in the art could have been combined to produce an efficient transformation method.

COMBINING PRIOR ART ELEMENTS TO YIELD PREDICTABLE RESULTS

The prior art references relied on teach each element claimed with the exception of transformation of soybeans, transformation of meristematic tissue, and the use of glyphosate as a selection agent. Transformation of soybeans was well-known in the art at the time of filing (see Applicant's reference to US Patent 5,914,451 in paragraph 0042 on page 11 of the instant specification), and there does not appear to be any recited method steps or recited materials that are specific to the transformation of soybeans in the instant claims. Transformation of meristematic tissue and the use of glyphosate as a selection agent were also well-

known in the art at the time of filing. Therefore, all elements of the instant invention were known in the art prior to the filing of the instant application.

One of ordinary skill in the art could have combined the elements as claimed, and each of the elements would have performed their known functions.

One of ordinary skill in the art would have predicted that the result would be a reasonably efficient method of transformation for dicots, soybeans, or cotton. Therefore, the results achieved by the instant invention are not unexpected.

APPLICANTS ASSERTIONS AND ARGUMENTS

The Applicant asserts in the specification that the instant invention is a method that is based on the observation that the presence of the gene of interest in the roots indicates a germline transformation event (see paragraph bridging pages 2-3 of the specification). The assertion appears to be related to the difficulties in selection of transgenic plants due to the generation of chimeras which do not pass the transformation event to their progeny (see paragraph bridging pages 1-2 of the specification). Chimeras are one type of "escape" (see page 4, paragraph 0017), and can be thought of as a type of false positive. The Applicant argues that similar false positives are identified by assaying leaf tissue, and this results in wasted resources and time as plants are carried forward that do not give rise to transgenic progeny (see paragraph bridging pages 5-6 of the response filed on May 19, 2005). The

Applicant asserts that their analysis of R1 plants from multiple constructs indicated a 75-100% correlation with plants rooting on glyphosate and germline transformation (see paragraph bridging pages 5-6 of the response filed on May 19, 2005).

As it relates to the limitation in the claims of "obtaining an extract of root tissue from the transformed plant and assaying the extract for the presence of the nucleic acid sequence", this assertion is not supported by data in the instant specification. Table 4 indicates either 70% or 74% correlation between root assay positives and germline positives (see Table 4, bridging pages 20-21 of the specification). Table 3 indicates either 81% or 84% correlation between growing putative transformants on selectable media and germline positives (see Table 3, page 20 of the specification). Therefore, these data do not support any greater correlation between root assay positives and germline when compared to the correlation between growing on selection media and germline positives.

The prior art clearly teaches growing the putative transformants on selectable media. The prior art also teaches assaying extracts from roots for the presence of a transgene. In the absence of any evidence that assaying extracts from roots is a critical step that provides an unexpected result, the claimed method is merely an obvious variant of methods already taught in the prior art that utilize elements already known in the prior art. Therefore, claims 1-19 are unpatentable over Firoozabady et al in view of Jefferson et al.

Double Patenting

8. Claims 1-19 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3, 5-8, and 10-12 of U.S. Patent No. 5,914,451 (Martinell et al, issued on June 22, 1999, assignee: Monsanto Company) in view of Jefferson et al (The EMBO Journal (1987), Vol. 6, pp.3901-3907).

The claims are drawn to a method for early identification of germline transformed plants.

None of the elements recited in the claims are novel (see below for an item-by-item account of references from the prior art that teach these elements), and there is no indication of a particular element that is critical. In the absence of any evidence of criticality or unexpected results, any combination of these elements is an obvious variant of methods taught and claimed by Martinell et al modified to include elements taught by Jefferson et al.

In the prior art, Martinell et al teach many of the limitations recited in the instant claims. They teach the transformation of soybeans (which are dicots) (see entire document). They teach the use of meristematic tissue for transformation via particle bombardment (see column 8, lines 15-45). They teach culturing the transformed tissue to produce shoots (see column 8, lines 59-67). They teach culturing the transformed shoots on bean rooting medium to induce the growth of

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roots (see column 9, lines 1-17). They teach that the root medium contained 0.025 mM glyphosate, which is an herbicide that is used as a selectable marker for transformants expressing the EPSP gene (see column 9, lines 1-5; and column 5, lines 25-41). Therefore, the roots were grown in the presence of a selection agent that corresponds to the EPSP gene-product that is a protein that confers resistance to glyphosate.

They teach that genetically engineered soybeans can have advantageous qualities; such as higher yields, pest resistance, enhanced nutritional value, and improved storage qualities, which are traits that can be conferred to a soybean by transformation with a plant expressible construct (see column 3, lines 4-11). They teach a plasmid encoding the EPSP gene (referred to as CP4) as well as encoding β -glucuronidase (GUS) (see column 9, Table 1, and lines 46-58); therefore the plant expressible construct taught by Martinell et al comprised two nucleic acid sequence each encoding a protein. They screened for the presence of the protein encoded by the CP4 gene by ELISA (see paragraph bridging columns 9-10).

Martinell et al do not teach obtaining an extract of root tissue from the transformed plant tissue and assaying the extract for the presence of the nucleic acid sequence. They do not teach the detection of a nucleic acid by PCR, RT_PCR, or Southern Blot. They do not teach the NPTII gene or kanamycin selection. They do not teach transformation of cotton.

In the prior art, Jefferson et al teach the remaining limitations from the claims with the exception of transformation of cotton. They teach obtaining an extract of root tissue from transformed plants and assaying for reporter activity that indicated the presence of the nucleic acid sequence (see page 3903, Figure 2). They teach detection of the nucleic acid by Southern Blot (see page 3904, Figure 3). They teach the NPTII gene which is known in the art to confer resistance to kanamycin (see page 3901, right column). They teach kanamycin selection (see page 3906, right column, second paragraph).

The prior art references relied on teach each element claimed with the exception of transformation of cotton. Transformation of cotton was well-known in the art at the time of filing (see Applicant's reference to McCabe and Martinell in paragraph 0164 on page 21 of the instant specification), and there does not appear to be any recited method steps or recited materials that are specific to the transformation of cotton in the instant claims. Therefore, all elements of the instant invention were known in the art prior to the filing of the instant application.

One of ordinary skill in the art could have combined the elements as claimed, and each of the elements would have performed their known functions.

One of ordinary skill in the art would have predicted that the result would be a reasonably efficient method of transformation for dicots, soybeans, or cotton. Therefore, the results achieved by the instant invention are not unexpected.

The prior art clearly teaches growing the putative transformants on selectable media. The prior art also teaches assaying extracts from roots for the presence of a transgene. In the absence of any evidence that assaying extracts from roots is a critical step that provides an unexpected result, the claimed method is merely an obvious variant of methods claimed by and taught in Martinell et al (US Patent No. 5,914,451) that utilize elements already known in the prior art. Therefore, claims 1-19 are unpatentable over Martinell et al in view of Jefferson et al under the judicially created doctrine for non-statutory double patenting.

9. No claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cathy K. Worley whose telephone number is (571) 272-8784. The examiner is on a variable schedule but can normally be reached on M-F 10:00 - 4:00 with additional variable hours before 10:00 and after 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CKW
8/17/07

/Medina A. Ibrahim/
Primary Examiner
Art Unit 1638